

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Antimicrobial Drugs Advisory Committee and
the Drug Safety and Risk Management Advisory Committee***

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

November 5, 2015

QUESTIONS TO THE COMMITTEE

1. **VOTE:** Do the benefits and risks of the systemic fluoroquinolone antibacterial drugs support the current labeled indication for the treatment of acute bacterial sinusitis (ABS)?
 - a. Following your vote, provide specific recommendations, if any, concerning the indications for treatment of ABS and safety information, including the constellation of adverse reactions that were characterized as a fluoroquinolone associated disability (FQAD)
2. **VOTE:** Do the benefits and risks of the systemic fluoroquinolone antibacterial drugs support the current labeled indication for the treatment of acute bacterial exacerbation of chronic bronchitis in patients who have chronic obstructive pulmonary disease (ABECB-COPD)?
 - a. Following your vote, provide specific recommendations, if any, concerning the indications for treatment of ABECB and safety information, including the constellation of adverse reactions that were characterized as a fluoroquinolone associated disability (FQAD)
3. **VOTE:** Do the benefits and risks of the systemic fluoroquinolone antibacterial drugs support the current labeled indication for the treatment of uncomplicated urinary tract infection (uUTI)?
 - a. Following your vote, provide specific recommendations, if any, concerning the indications for treatment of uUTI and safety information, including the constellation of adverse reactions that were characterized as a fluoroquinolone associated disability (FQAD)